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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/668,248	09/24/2003	Eckard Weber	2009.0010005	4290

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STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.
1100 NEW YORK AVENUE, N.W.
WASHINGTON, DC 20005

EXAMINER	
WINSTON, RANDALL O	
ART UNIT	PAPER NUMBER
1655	
MAIL DATE	DELIVERY MODE
11/26/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/668,248	WEBER ET AL.	
	Examiner	Art Unit	
	Randall Winston	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 September 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *35-37 and 39-45* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *35-37 and 39-45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 09/10/2008 has been entered.

Claims 35-37 and 39-45 have been examined on the merits.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 35-37 and 39-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grenfell et al. (US 6416323) in view of Watt-Smith (US 4659714) for the reasons set forth in the previous OFFICE ACTION which are restated below.

Applicants claim a dental cartridge said cartridge fits into a standard local anesthetic syringe wherein the cartridge contains a composition consisting essentially of phentolamine mesylate in various amounts and a pharmaceutical carrier.

{Please note: In *PPG Industries*, 156 F.3d at 1355, 48, USPQ2d at 1355, it discloses that for the purpose of searching for and applying prior art under 35 USC 102

and 103, absent clear indication in the specification or claims of what the basic and novel characteristics actually are "consisting essentially of" will be constructed as equivalent to "comprising." (see, e.g. MPEP 2111. 03).}

Grenfell et al. teach a dental cartridge said cartridge fits into a standard dental local syringe wherein the cartridge contains a composition consisting essentially of substances to improve local anesthesia for dentistry or oral surgery (please note that a pharmaceutical carrier is known to be water) (see, e.g. abstract and column 9 lines 18-33). Grenfell does not teach the claimed substance of the active ingredient of phentolamine mesylate within the cartridge that fits into a standard dental local syringe.

Watt-Smith benefically teaches that phentolamine or its salts is useful to improve local anesthesia for dentistry or oral surgery (please note that phentolamine and its salts improved local anesthesia for dentistry or oral surgery as being used as an alpha-adrenoreceptor blocking agent to reduce prolongation of anesthesia by vasoconstrictor) (see, e.g. entire patent including Table 1).

One of ordinary skill in the art of creating the claimed invention would have been motivated to substitute Grenfell's claimed active ingredient substance within its claimed dental cartridge with the active ingredient of a phentolamine or its salts as taught by Watt-Smith because the above combined two references as a whole would create the claimed invention's dental cartridge said cartridge fits into a standard dental local syringe wherein the cartridge contains a composition consisting essentially of phentolamine mesylate to improve local anesthesia for dentistry or oral surgery. Moreover, according to Watt-Smith's Table 1, it is clear to the Examiner that most of the

reduction of the prolonged anesthetic effect takes place between 0mg to 1mg. It is also clear to Examiner that between 1mg to 3mg that the reduction of the prolonged anesthetic appears to be approximately linear and only slightly changing. Therefore, it would be obvious to one of ordinary skill in the art to modify Watt-Smith's phentolamine amount by lowering the disclosed amount to under 1mg, e.g. to the instantly claimed amounts of about 0.0018mg and about 0.45 mg, because according to Watt-Smith Table 1, an amount under 1mg is expected to have a beneficial effect of the reduction of the prolonged anesthetic effect not significantly different than a amount over 1mg which is nearly linear. Furthermore, the adjustment of other convention working conditions (e.g. although it is well known to one of ordinary skill in the art that in order for the cartridge to be able to fit into standard dental syringe, the cartridge would have to have a volume of between 1.6 ml and 1.8 ml), is deemed a matter of judicial selection and routine optimization which is well within the purview of the skilled artisan.

Accordingly, the invention as a whole is *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Applicant's arguments filed on 06/10/2008 have been carefully considered but they are not deemed persuasive. Applicant argues Grenfell discloses that the dental cartridge may contain an anesthetic but there is no teaching that an alpha adrenergic receptor antagonist may be present. Thus, Examiner has not pointed to any particular reason why one of ordinary skill in the art would replace the anesthetic, vaccine, or

other therapeutic or diagnostic agent disclosed in Grenfell with an alpha adrenergic receptor antagonist.

Although Applicant argues that Examiner has not pointed to any particular reason why one of ordinary skill in the art would replace the anesthetic, vaccine, or other therapeutic or diagnostic agent disclosed in Grenfell with an alpha adrenergic receptor antagonist, Applicant argument is not found persuasive because it is well known to one ordinary skilled in the art that one would need to administer phentolamine as taught by Watt-Smith to a subject in need thereof, and Grenfell provides such a generically useful device. For example, Grenfell provides a broad teaching than just about any dentally desired material can be injected by the dentist using this device to improve local anesthesia for dentistry or oral surgery. Furthermore, Watt-Smith teaches that phentolamine or its salts is useful to improve local anesthesia for dentistry or oral surgery. Therefore, since one ordinary skilled in the art would need to administer phentolamine as taught by Watt-Smith to a subject in need thereof and Grenfell provides such a generically useful device, one of ordinary skill in the art of creating the claimed invention would have been motivated to substitute Grenfell's claimed active ingredient substance within its claimed dental cartridge with the active ingredient of a phentolamine or its salts as taught by Watt-Smith because the above combined two references as a whole would create the claimed invention's dental cartridge said cartridge fits into a standard dental local syringe wherein the cartridge contains a composition consisting essentially of phentolamine mesylate to improve local anesthesia for dentistry or oral surgery.

Moreover, Applicant argues that Watt-Smith discloses concentrations of phentoamine in Table I not unit doses. Therefore, the concentrations tested in Watt-Smith should be compared to the concentrations, rather than the unit doses.

Although Applicant argues that Watt-Smith discloses concentrations of phentoamine in Table I not unit doses, Applicant argument is not found persuasive because Applicant is not claiming a method of using a claimed active ingredient of claimed ranges but a dental cartridge and/or composition consisting essentially of a claimed active ingredient of a claimed range concentration. Therefore, since Watt-Smith teaches the same claimed active ingredient (i.e. phentolamine) of the same claimed range concentrations (i.e. within Table 1, the concentration of 0mg to 3mg) as the claimed invention's active ingredient and range concentration, Watts-Smith reads on the claimed invention because the device and/or container consisting essentially of the active ingredient such as phentolamine (e.g. a container that fits into a standard dental local anesthetic syringe) is placed into are not given patentable weight for unit dose purposes because the device and/or container do not change the composition and/or the active ingredient of phentolamine within the device. For example, if one of ordinary skill in the art places sugar into a sugar bowl, the sugar will still be the same solution and/or composition. The sugar bowl has not changed the sugar. Therefore, the device and/or container the sugar is placed into are not given patentable weight for unit dose purposes.

Lastly, Applicant argues Watt-Smith teaches away from the use of lower doses and concentrations because most dose-response curves are not linear.

Although Applicant argues Watt-Smith teaches away from the use of lower doses and concentrations because most dose-response curves are not linear, Applicant argument is not found persuasive because it is clear to the Examiner that most of the reduction of the prolonged anesthetic effect takes place between 0mg to 1mg. It is also clear to Examiner that between 1mg to 3mg that the reduction of the prolonged anesthetic appears to be approximately linear and only slightly changing. Therefore, it would be obvious to one of ordinary skill in the art to modify Watt-Smith's phentolamine amount by lowering the disclosed amount to under 1mg, e.g. to the instantly claimed amounts of about 0.0018mg and about 0.45 mg, because according to Watt-Smith Table 1, an amount under 1mg is expected to have a beneficial effect of the reduction of the prolonged anesthetic effect not significantly different than a amount over 1mg which is nearly linear.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Randall Winston whose telephone number is 571-272-0972. The examiner can normally be reached on 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

RW

/JON P WEBER/

Supervisory Patent Examiner, Art Unit 1657